UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

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ROBERT JONES and KRISTA JONES,

Plaintiffs,

-against-

SYNTHES USA SALES, LLC, SYNTHES USA PRODUCTS, LLC, JOHN DOES 1-5, and ABC CORP. 1-5,

Defendants.

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Civil Action No.: 08 CV 2060 (JAP)

NOTICE OF MOTION

DOCUMENT ELECTRONICALLY FILED

Oral Argument Requested
Motion Date: May 3, 2010

PLEASE TAKE NOTICE that, upon the Affirmation of Christopher Keale dated February 26, 2010 and the exhibits annexed thereto, the Rule 56.1 Statement of Material Facts, and Memorandum of Law in support, all simultaneously submitted herewith, the defendants, SYNTHES USA SALES, LLC and SYNTHES USA PRODUCTS, LLC, by their attorneys, Sedgwick, Detert, Moran & Arnold LLP, will move this Court, on the 3rd day of May, 2010, before the Hon. Joel Pisano, U.S.D.J., at the United States District Courthouse for the District Of New Jersey, Clarkson S. Fisher Building, 402 East State Street, Trenton, New Jersey 08608, for an Order, pursuant to Rule 56 of the Federal Rules of Civil Procedure, granting summary judgment in favor of defendants dismissing plaintiff's

Complaint with prejudice; or, in the alternative, an Order, pursuant to Federal Rules of Evidence Rules 702 and 703, precluding plaintiff's expert, Warren Lieberman, from testifying in this matter, or for a *Daubert* hearing to assess the admissibility of the opinions proffered by this expert, together with such other and further relief as this Court may deem just and proper.

PLEASE TAKE FURTHER NOTICE that answering papers, if any, must be served by March 26, 2010 and any reply by April 9, 2010.

Dated: New York, New York
February 26, 2010

Respectfully Submitted,

By: s/ Christopher Keale
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Barry L. Gerstman, Esq.
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AFFIRMATION IN SUPPORT

DOCUMENT ELECTRONICALLY FILED

Christopher Keale affirms the following under penalty of perjury:

1. I am a member of the law firm of Sedgwick, Detert, Moran & Arnold LLP, attorneys for defendants, SYNTHES USA SALES, LLC and SYNTHES USA PRODUCTS, LLC (hereinafter referred to collectively as "Synthes"). I am fully familiar with the facts and circumstances of this matter.

2. This affirmation is submitted in support of Synthes' motion for an Order, pursuant to Rule 56 of the Federal Rules of Civil Procedure, granting summary judgment in favor of Synthes dismissing plaintiff's Complaint with prejudice; or, in the alternative, for an Order, pursuant to Federal Rules of Evidence Rules 702 and 703, precluding plaintiff's expert, Warren Lieberman,

from testifying in this matter, or for a *Daubert* hearing to assess the admissibility of the opinions proffered by this expert.

3. The following exhibits are submitted in support of the motion:

A. Summons and Complaint

B. Notice of Removal

C. First Amended Summons and Complaint

D. Synthes' Answer to First Amended Complaint

E. Warren Lieberman's Curriculum Vitae

F. Warren Lieberman's report dated June 17, 2009

G. Warren Lieberman's supplemental report dated September 24, 2009

H. Affidavit of Joel Spielman, M.D. with attached reports dated July 8, 2009 and December 7, 2009

I. Affidavit of Lyle Zardiackas, Ph.D., FADM with attached reports dated July 10, 2009 and December 8, 2009

J. July 22, 2005 Operative Report from St. Francis Medical Center

K. August 4, 2006 Operative Report from Robert Wood Johnson University Hospital

L. Synthes Package Insert for its Internal Fixation Devices

M. Anterior Tension Band Technique Guide

N. Design drawings and manufacturing specifications for Anterior Tension Band System

O. FDA 510(k) for Anterior Tension Band System with testing results

P. Selected Office Records of Trenton Orthopaedic Group

Q. Deposition Transcript of Plaintiff Robert Jones

R. Deposition Transcript of Mark Levine, M.D.

S. Deposition Transcript of Warren Lieberman (Days I and II)

T. Deposition Transcript of Benjamin Barrall

U. Excerpt from Biomaterials in Reconstructive Surgery (1983), *Failure Analysis of Metallic Orthopedic Devices*, Chapter 5, p. 123

V. Excerpt from *Manual of Internal Fixation* (3d Edition – 1991), p. 672

W. *Validating the Shot Peening Process*, The Shot Peener (2008)

4. This is a product liability action filed by plaintiff Robert Jones against defendant Synthes relating to the Synthes Anterior Tension Band System ("ATB"). (See First Amended Summons and Complaint at Ex. C) Plaintiff claims that an ATB implanted by his physician, Dr. Marc Levine, during July 2005 spinal fusion surgery was defective because two of the four ATB screws broke ten months after the surgery.

5. Synthes moves for summary judgment on the grounds that plaintiff has no reliable evidence that the ATB was defective in manufacture or design, or that Synthes did not adequately warn about the risks of the device. In addition,

since plaintiff has failed to retain a medical expert, he cannot contest the testimony from plaintiff's surgeon, Dr. Levine, as well as Dr. Joel Spielman, a spinal surgeon retained by Synthes, that 1) plaintiff's failure to fuse caused breakage of the ATB's screws; 2) that the failure to fuse necessitated revision surgery; 3) that plaintiff had pre-existing disc disease at other levels of his spine that were not treated during his surgery; 4) that plaintiff's current complaints are not related to the breakage of the ATB's screws and; 5) that the limited goals of the surgery were achieved. Accordingly, plaintiff cannot make out a *prima facie* case of product liability under New Jersey's Product Liability Act, N.J.S. 2A:58C-1 through C-7 ("NJPLA").

6. While Synthes believes that it has independent grounds for summary judgment even if plaintiff's expert, Mr. Lieberman, were permitted to testify, it is respectfully submitted that Mr. Lieberman's opinions must be excluded under *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 589 (1993) because he lacks sufficient education, experience and training in the field of internal fixation devices, biomaterials, orthopedics and/or spinal fusion surgery to offer reliable testimony on these topics.

7. As to methodology, his alternative design/manufacturing methods, i.e. shot peening, gray anodization and dye penetrant inspection, which he claims would have improved the fatigue life of the ATB and/or revealed a flaw in the ATB, are not supported by reliable methodology nor validation. Mr. Lieberman

has neither tested nor validated these methods to determine whether they would improve fatigue life or for safety, feasibility or efficacy. He has not submitted the application of these methods to cancellous bone screws of the type used in the ATB for peer review. He cannot cite any scientific studies supporting the use of these methods for cancellous bone screws. He has not performed a single test to determine whether or not these methods would negatively affect the special thread and/or locking mechanisms of the ATB screws and thus interfere with safety, form, fit and function. He fails to cite a single FDA or industry standard that Synthes allegedly violated in its testing of the ATB prior to its introduction. He fails to rule out the generally accepted proposition that internal fixation devices such as the ATB fail for non-negligent reasons including but not limited to a patient's failure to achieve bony fusion, surgical technique, a patient's underlying medical condition, post-surgical activity and a patient's failure to comply with physician instructions. He does not address that, in plaintiff's case, the ATB screws broke as a result of plaintiff's failure to achieve bony fusion. Given the foregoing, his opinions and methodology are unreliable, speculative, do not "fit" the facts of the case, are not generally accepted and should be precluded under Daubert.

Procedural History

8. This is a products liability action that was originally filed in the Superior Court of New Jersey, Mercer County on March 31, 2008. (Ex. A) On

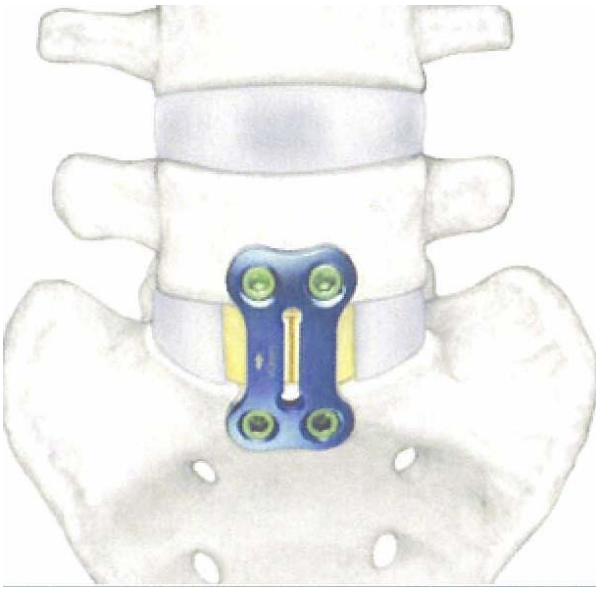
April 28, 2008, Synthes removed the case to the United States District Court for the District of New Jersey based on diversity jurisdiction under 28 U.S.C. Section 1441(a). (Ex. B) On March 12, 2009, plaintiff filed a First Amended Complaint to address a corporate status change at Synthes. (Ex. C) Plaintiff's First Amended Complaint asserts causes of action against defendant Synthes sounding in products liability, negligence, breach of warranty and consumer fraud. (Ex. C) Synthes denied all liability in its Answer to the First Amended Complaint filed on November 13, 2009. (Ex. D)

Statement of Facts

9. The ATB is a prescription medical device consisting of a metallic plate and four cancellous bone screws[1] sold in a variety of lengths. See Figure 1 below. The ATB is indicated for spinal fusion surgery for the treatment of lumbar and/or lumbosacral spine (L5-S1) instability resulting from, among other causes, degenerative disc disease. (See ATB Technique Guide, p. 2 at Ex. M)

[1] A cancellous screw design, as used for the ATB, has a deep thread profile with very sharp edges at the crest of the thread. (Zardiackas Aff., ¶ 10 at Ex. I) The deep threads are necessary to provide purchase in the cancellous bone which is a light, pourous bone enclosing large spaces that give it a honeycombed appearance. http://www.britannica.com

Figure 1

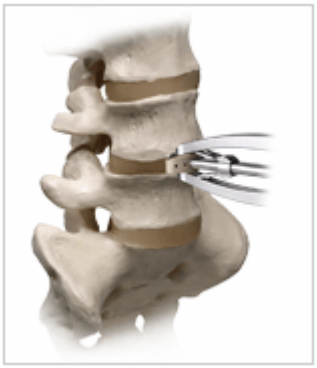


10. Spinal fusion surgery involves an attempt to fuse two vertebrae together to reduce motion and pain in a diseased or injured segment of the spine. (See Deposition of Marc Levine, M.D., p. 15-16 at Ex. R) Spine surgeons utilize a variety of methods and hardware to try to achieve fusion between two vertebrae. The surgery can be performed from the front of the patient's body (an anterior approach) or from the back (a posterior approach). The surgery at a minimum involves 1) a diskectomy: removal of the damaged disc which lies between two vertebrae; and 2) the implantation of an interbody device/spacer and graft material in the space between the two vertebrae where the disc was removed and, where it

is hoped, that bony fusion will occur. In certain cases, a surgeon may also decide to use other hardware such as a metal plate and/or screws, like the ATB when the surgery is performed using an anterior approach, or pedicle screws and/or rods when the surgery is performed using a posterior approach, or both systems together, in order to provide supplemental support for the interbody device and graft material. Whether or not supplemental support is used, the key to achieving fusion of two vertebrae are the spacer and graft material, not the ATB, which merely serves as supplemental fixation for the spacer and graft construct. (Spielman Aff. ¶8 at Ex. H)

11. When a surgeon elects to use the Synthes ATB, it is implanted in the lumbar or lumbosacral region of a patient's spine via an anterior approach. The ATB is used to provide supplemental support for an interbody device/spacer and graft material (in plaintiff's case a Globus Medical 11 mm spacer and 2 Medtronic Infuse sponges. Neither the spacer nor the sponges are Synthes products.) which are implanted between two vertebrae in place of the damaged disc which is removed by the surgeon. See Figure 2 showing an interbody device/spacer and Figure 3 showing the location of the spacer between the two vertebrae.

Figure 2 **Figure 3**



12. The risk of a particular patient not achieving bony fusion across the intra-vertebral space is well known in the field of spinal fusion surgery. (*See* Spielman Aff. ¶ 5 at Ex. H) It is generally accepted in the fields of metallic internal fixation devices, biomaterials, orthopedics and fusion surgery that internal fixation devices are intended solely for temporary fixation, that no internal fixation device will last indefinitely and that internal fixation devices are subject to cyclical loading. (Id.) These devices will ultimately fail in the presence of an incomplete fusion/nonunion. *Id.* This is commonly known as the "implant race" i.e. the race between bone fusion and implant failure. If fusion occurs the implant will not break. If fusion is delayed or non-successful, the implant will break from metal fatigue.

13. Each shipment of Synthes product came with an insert labeled "FOR THE PERSONAL ATTENTION OF THE OPERATING SURGEON" (the

"Package Insert") that set forth the warnings that apply to all such metallic fixation devices. The Package Insert warned of the very risks complained of by plaintiff. It stated:

- [t]hese implants are intended only to assist healing and **not** intended to replace normal bony structures.
- If there is delayed union or nonunion of bone in the presence of weight bearing or load bearing, the implant could eventually break due to metal fatigue.
- Factors such as the patient's weight…,and adherence to weight-bearing or load-bearing instructions have an effect on the stresses to which the implant is subjected, and therefore on the life of the implant. It is important to note that these implants may break at any time if they are subjected to sufficient stresses.
- These devices can break when subjected to the increased loading associated with delayed union or nonunion.
- Metallic implants can loosen, fracture, corrode, migrate, cause pain, or stress shield bone even after a fracture has healed. (See Exhibit L) [Emphasis in original]

14. The general acceptance of the "implant race" is evidenced by its inclusion in numerous orthopedic textbooks and biomaterial literature. (*See* Ex. U and Ex. V)

15. The "implant race" is also documented by plaintiff's surgeon, Dr. Levine, who testified that he learned this basic tenet of orthopedic surgery during his residency. He testified as follows:

Q. There are some people who seem to think that a plate is stronger than bone; is that correct?

A. Well, it can be stronger than bone for a finite amount of time, but over a cyclical loading, the problem with a plate and any object that you place in the body is that it doesn't have a turn over capacity. For instance, our bone, you know we have a body that, thankfully, it would turn over bone and essentially give you fresh bone as it is turning over. Whereas any instrumentation that you are putting in the body doesn't have that capacity. It has a limited cyclical loading capacity that we see in other orthopedics; knee replacements. All these things have a certain life expectancy before they are going to wear out. I don't think the spine is any different in that, I think, it is more the cyclical loading that becomes problematic in this race to get a solid fusion or stability before the potential problems of hardware failing.

Q. You mentioned a race to fusion and you explained it as a race between bone union and implant failure; correct?

A. Correct.

Q. Where did you learn about that race?

A. Well, the jargon is more illustrative than technical, obviously, but there are certainly, in the biomechanics of most implants of man-made implants, their cyclical loading to failure that goes on in that study. So it's part of the orthopedic training to know that there is a certain cyclical loading concerns with any type of metal implant.

Q. Is this a well known concept, the race between fusion and failure?

A. I don't know if I can say that my jargon which -- trying to be illustrative, I don't know if I would say people would use that same jargon. I think the concept of cyclical loading and failure of implants and the possibility of failure in situations where bone does not heal, whether it is in the spine or elsewhere is well known, yes.

Q. That is a well known risk of orthopedic implants; is that correct?

MS. CHELIUS: The possibility of failure.

THE WITNESS: I believe so, yes. (Deposition of Mark Levine, M.D., p. 21 - 22 at Ex. R)

Plaintiff's Medical History

16. In this case, plaintiff underwent anterior lumbar interbody fusion surgery on July 22, 2005 performed by Dr. Levine at St. Francis Medical Center. (See July 22, 2005 Operative Report at Ex. J) The surgery involved a Globus Medical 11 mm interbody device/spacer, 2 Medtronic Infuse sponges and a Synthes ATB. (Id.)

A. Plaintiff had severe and debilitating back pain prior to surgery.

17. Plaintiff's relevant medical history shows that he is a 47 year-old man with a pre-surgical history of lower back pain with radiation stemming from multiple back injuries that occurred between September 1998 and August 2004 while he was working as a corrections officer. (See Ex. P – SYNTH000203-SYNTH463)

18. In March 2004, after years of unsuccessful treatment with steroid injections, plaintiff began treating with Dr. Marc Levine of Trenton Orthopaedic Group. (SYNTH000218 at Ex. P) At that time, plaintiff testified that his lower back "would throb, tightening and stabbing pain, and it would go down my right leg…It was steadily getting worse." (Jones Dep., p. 116 at Ex. Q) Dr. Levine made an initial diagnosis of low back pain with degenerative disc disease at L5-S1

as well as congenital stenosis at L4-5 to a greater degree than L3-4. (SYNTH000218 at Ex. P)

19. In July 2004, following another injury at work, plaintiff testified that his pain level had increased from "moderately severe to falling-down-crying severe." (Jones Dep., p. 125 at Ex. Q) His overall pain distribution was now 80% low back and 20% right leg whereas it had previously been 60% lower back and 40% right leg. (SYNTH000219 at Ex. P)

20. In an August 23, 2004 office note, Dr. Levine wrote that plaintiff's "low back pain is significant enough that he wishes to pursue surgical intervention. The pain is so severe that the other day he left his children to go upstairs to lay down so that he would not cry in front of them. The pain is severe regardless of occupation." (SYNTH000257 at Ex. P)

B. Plaintiff had multi-level disc disease.

21. In August 2004, in order to determine a course of surgical treatment (decompression v. fusion surgery), Dr. Levine ordered that a discogram be performed on plaintiff. (SYNTH000259 at Ex. P) A discogram is a diagnostic procedure in which x-ray dye or contrast material is injected into the discs of the spine in order to determine whether a patient's pain is from diseased disc or some other cause.

22. The August 2004 discogram showed that plaintiff had multi-level disc disease with pain of 7 out of 10 to 10 out of 10 at several levels of his spine. The discogram report documents the following: 1) L2-3 with grade 0 anular degeneration and disruption; mild discorant back pain; 2) L3-4 with grade II anular degeneration and grade II disruption; concordant low back, right buttock and upper leg pain (7/10); 3) L4-5 with grade 0 anular degeneration and disruption; no pain; and 4) L5-S1 with grade I anular degeneration and focal grade III disruption; exact low back and right leg pain (10/10). (SYNTH000415-418 at Ex. P)

C. The goal of surgery was the reduction not elimination of plaintiff's back pain.

23. Following the discogram, Dr. Levine discussed with plaintiff performing an L5-S1 anterior lumbar interbody fusion. He testified that the surgery is considered successful if a patient "had improvement of 50 percent of their pain." (Levine Dep., p. 42 at Ex. R) He also specifically informed plaintiff that the findings of disc disease at other levels of his spine "could cause residual pain, even despite surgery at the L5-S1 level." (Levine Dep., p. 58) He also warned plaintiff that he may not be able to return to work as a corrections officer. (Levine Dep., p. 59-60)

24. Dr. Levine's office notes dated August 23, 2004 also document a specific discussion with plaintiff that attempting to fuse the L5-S1 vertebrae would not alleviate plaintiff's discomfort and the pathology at the L3-L4 level.

(SYNTH000257 at Ex. P) Dr. Levine noted that "there may be some residual discomfort from that pathology in the future." (Id.) Plaintiff testified that he recalled these discussions and knew the goal of the surgery was to alleviate rather than eliminate his pain. (Jones Dep., p. 238-239 at Ex. Q)

25. Dr. Levine's notes document a discussion with plaintiff concerning his ability to return to work. A note dated August 23, 2004 states "the family clearly understands that the goal of surgery is to help alleviate some of his back discomfort and would not in all likelihood allow him to return to any type of heavy lifting work. He already understands that his career as a corrections officer may be over due to his current back discomfort as well as the non-probability of this surgery allowing him to return to that type of strenuous work." (SYNTH000257 at Ex. P)

26. Plaintiff decided to proceed with surgery with Dr. Levine. A note from Dr. Levine dated May 9, 2005, a month prior to surgery, states that plaintiff "fully understands that the goal of surgery is to alleviate some of his pain and cannot be guaranteed to alleviate all of his pain…He will never be pain free as he understands." (SYNTH000252 at Ex. P)

D. Dr. Levine discussed the risks of surgery including possible failure to fuse and device breakage.

27. Dr. Levine testified that he specifically warned plaintiff about the risks of the surgery including "failure of fusion" and "failure of the

instrumentation." (Levine Dep., p. 51-52 at Ex. R) His contemporaneous office notes also record a discussion of these risks. (SYNTH000257 at Ex. P)

28. As to the failure to fuse, Dr. Levine testified that:

> "Unfortunately not all fusions fuse. What we do is we put in material and we hope the material will harden and achieve a solid fusion over time, but there's certainly a rate of non-fusion in the spine as well as elsewhere in the body for all orthopedic procedures. A fracture, the fracture doesn't always have fusion and you get a malunion, and the same thing occurs when you do a fusion of the spine, you can get a non-solid fusion."
>
> (Levine Dep., p. 55-56 at Ex. R)

29. As to failure of the instrumentation, Dr. Levine testified that:

> "Instrumentation historically can fail. No matter what part of the body you are doing an orthopedic procedure in, whether it is the spine or elsewhere, instrumentation can break, can fail. Over time, short time, long time. The explanations aren't always apparent, but it is certainly part of the accepted outcomes of putting in hardware and instrumentation into the spine."
>
> (Levine Dep., p. 56 at Ex. R)
>
> * * *
>
> "I think that there's an accepted understanding in orthopedic surgery that the mechanical devices that are put in, can have a propensity to fail over time, if a solid fusion is not achieved, because the increased cyclical loading that is now – not being borne by the fusion, is now borne by the devices implanted and may have a higher propensity to fail at the time above."
>
> (Levine Dep., p. 95 at Ex. R)

30. Dr. Levine performed surgery on plaintiff on July 22, 2005 at St. Francis Medical Center. The surgery involved: 1) an L5-S1 anterior diskectomy where the disc between the L5-S1 vertebrae was removed; 2) an L5-S1 anterior lumbar interbody fusion where a non-Synthes, Globus 11 mm interbody device was inserted in place of the removed disc along with 2 Infuse sponges containing material designed to encourage fusion and bone growth in the vertebral space; and 3) the implantation of the Synthes ATB system at L5-S1 consisting of a 41 mm plate, two 24 mm screws and two 26 mm screws to provide supplemental support for the interbody device and graft material. (See July 22, 2005 Operative Report at Ex. J)

31. Between August 2005 and May 2006, plaintiff had multiple follow-up visits with Dr. Levine to track his progress. During several of these visits, the placement of the instrumentation was checked usually via x-ray. On August 8, 2005, Dr. Levine noted that plaintiff was "doing quite well overall." (SYNTH000250 at Ex. P)

32. On September 8, 2005, a x-ray showed that the instrumentation was in place. (SYNTH000249 at Ex. P) Plaintiff reported pain but was "dramatically improved" and "even on his worse days, was better than it was on his best day prior to surgery." (Id.)

33. On October 24, 2005, plaintiff stated to Dr. Levine that he still gets some aches and pains in his back as well as his legs. An x-ray showed "good placement of the graft as well as instrumentation." (SYNTH000248 at Ex. P)

34. On December 5, 2005, almost six months post-surgery, plaintiff reported that "prior to surgery his biggest complaint was right sided back pain and some right buttocks pain, which has largely resolved…he is having some left low back pain and some left buttocks pain." (SYNTH000247 at Ex. P) An x-ray showed the instrumentation was still in place. (Id.)

35. A February 9, 2006 note stated plaintiff reported "that physical therapy has been going well although he is still having low back discomfort." (SYNTH000245 at Ex. P)

36. On April 13, 2006, plaintiff reported to Dr. Levine that "his back pain continues to be tremendously improved following surgery." (SYNTH000239 at Ex. P) He was started on a work hardening program to see if he would be able to return to work. It was noted that plaintiff still had lower extremity symptoms during work hardening. (Id.)

E. Plaintiff reported a new onset of pain with numbness and tingling while the ATB and all instrumentation were documented to be in place.

37. On April 18, 2006, plaintiff reported to Dr. Levine that he "had the onset of back pain after bending over with numbness and tingling going down his legs." (SYNTH000238 at Ex. P) An x-ray taken that day showed "the

instrumentation to be in place. There is no evidence of retropulsion of his PEEK device or retropulsion of the screws into any canal region." (Id.) Dr. Levine prescribed steroids and suggested that plaintiff reduce the level of his physical therapy. (Id.)

38. A May 11, 2006 note from Dr. Levine states plaintiff "is still having some concerns regarding numbness and tingling predominantly in the back of the thighs of both legs. He also has some numbness in the feet. The numbness and tingling in the thighs is constant. He reported an event 2-3 weeks ago where he heard a snap in his back while bending with increased symptoms in his legs." (SYNTH000237 at Ex. P) An x-ray taken on May 11, 2006 showed "a failure of the left S1 screw of the ATB system with breakage within the bone." (Id.)

F. Dr. Levine testified that a lack of fusion caused breakage of the screws.

39. Dr. Levine testified that it was his opinion that complete bony fusion had not occurred in the ten month period following surgery which allowed enough micromotion to be present to cause a failure of the screws. He testified as follows:

> Q. At that point, did you understand that the back was not completely fused or there was non-fusion of the disc space?
>
> A. I think in general when you have broken hardware you have to at least believe there is a high incidence that a fusion is not solid, which would allow the ongoing micromotion that could possibly fail a piece of hardware.
>
> (Levine Dep., p. 90 at Ex. R)

* * *

> Q. Is the postsurgical ossification consistent with your view that there was not full union?
>
> A. It is, but frankly, if you have a failure of hardware you kind of have to…believe in absence of any other good explanation that there is a non-union or not a solid fusion that allowed micromotion to occur which fatigued the hardware that broke…
>
> (Levine Dep., p. 94)

40. Dr. Levine's contemporaneous office notes confirm his view that the failure to achieve complete bony fusion caused breakage of the screws. A May 18, 2006 note from Dr. Levine, following a CT scan of the lumbar spine, states: "based on the broken hardware, we have to assume that the fusion is not yet solid. For this reason, I am recommending a posterior stabilization procedure…" (SYNTH000236 at Ex. P) A follow-up note dated June 8, 2006 states that "the belief is to proceed with posterior stabilization for this anterior construct that may have some motion which would explain the failure of the plate screw." (SYNTH000234 at Ex. P)

41. On June 26, 2006, plaintiff saw Dr. Levine again. An x-ray taken on June 26, 2006 showed "breakage of both screws at the S1 level." (SYNTH000233 at Ex. P) A CT Scan report that was reviewed by Dr. Levine showed "some evidence of fusion mass within the interbody device" but it was difficult to fully assess because the plate was blocking the x-rays. (Id.) Dr. Levine further noted

"probable micro motion at the L5-S1 level." (Id.) The CT report stated that "I cannot clearly demonstrate bony bridging anteriorly." (Id.) This meant that complete bony fusion of the L5-S1 vertebrae had not occurred almost a year after surgery. Dr. Levine recommended proceeding with the implantation of posterior spinal instrumentation at L5-S1 with percutaneous pedicle screws. (Id.)

42. On August 4, 2006, plaintiff underwent posterior spinal fusion surgery by Dr. Levine at Robert Wood Johnson University Hospital (See August 2006 operative report at Ex. K) He thereafter had follow-up visits with Dr. Levine every thirty days. As of his deposition on February 2, 2009, plaintiff reported that his pain was different but better than before the surgery. (Jones Dep., p. 218 at Ex. Q) He rated his pain as a 3 out of 10 while prior to surgery he rated the pain as 7 or 10 out of 10. (Jones Dep., p. 212-218 at Ex. Q)

G. The ATB performed as intended by providing supplemental support for the interbody device.

43. Both Dr. Levine and Dr. Spielman testified or attested to the fact that the purpose of the ATB was to provide supplemental support for the interbody device and graft material that was inserted in place of the removed disc. (Levine Dep., p. 19 at Ex. R; Spielman Aff. ¶ 13 at Ex. H) Dr. Levine testified that spinal fusion can be achieved with an interbody device and graft material and no additional hardware. (Levine Dep., p. 18)

44. This view of the ATB as secondary support for the interbody device is confirmed by Dr. Spielman. Dr. Spielman states:

> Mr. Lieberman is incorrect as successful fusion can occur in the absence of the ATB system. In fact, L5-S1 fusion surgeries were successfully performed for decades prior to the introduction of the ATB system. The key to achieving fusion at L5-S1 are the spacer and graft material, not the ATB system, which merely serves as supplemental fixation for the spacer and graft construct. So long as the spacer and graft material remain in alignment and under compression the breakage of one or more screws of the ATB system at ten (10) months post-surgery had no adverse effect on the outcome of the surgery nor the likelihood of fusion taking place. Screw breakage would in fact allow for more compression of the graft site thus aiding rather than inhibiting fusion.
>
> (Spielman Aff. ¶ 8 at Ex. H)

H. There is no evidence that plaintiff sustained an injury from breakage of the ATB screws.

45. The post-surgical medical records and Dr. Levine's testimony confirm that the Globus interbody device as well as the ATB remained in alignment before and after the breakage of the screws. (See Levine Dep., p. 92-93 at Ex. R, SYNTH000232-000234; 000238 at Ex. P) Moreover, Dr. Levine testified the instrumentation, including the broken Synthes' screws which remain, are not impinging on any of plaintiff's nerves and are unrelated to plaintiff's current complaints of pain. He testified "as far as the hardware in his spine, the hardware

was nowhere in the vicinity of the nerves that would go down the left lower extremity to cause those symptoms." (Levine Dep., p. 79 at Ex. R)

Plaintiff's Expert Warren Lieberman

A. Mr. Lieberman's Opinion

46. Plaintiff retained Warren Lieberman, a former Boeing airplane engineer, to support his claims of product defect. Mr. Lieberman issued two reports dated June 17, 2009 and September 24, 2009 (See Exs. F and G, respectively) According to Mr. Lieberman's June 2009 report, he intends to testify that the "cancellous screw that failed in Mr. Jones' body that was implanted in the S1 disk was the result of a defectively manufactured Synthes screw." (Lieberman June 17, 2009 Report, p. 3 at Ex. F) He claims that the "defect is a result of the manufacturing error or the failure on the part of Synthes to properly test and understand all the normal variables the affect the fatigue strength of the ATB system…" (Id.) He concludes that "a defect in the screw caused the failure which could have been prevented by a more robust design providing a more resilient stronger screw." (Id.)

47. In Mr. Lieberman's supplemental report dated September 24, 2009, he opines that Synthes used the correct material for the ATB's screws i.e. a titanium alloy known as Ti-6A1-7Nb. (Lieberman September 24, 2009 report, p. 2 at Ex. G) He states that such material "is state of the art for surgical implants and its use

in this case is considered correct." (Id.) Mr. Lieberman opines, however, that Synthes should have investigated and used certain manufacturing methods such as shot peening and gray anodization which he claims would have increased the fatigue life of the screw. (Id. at p. 3-4) He also suggests that Synthes should have used an inspection method called a dye penetrant inspection which he claims may have detected a surface flaw in the screw if one was present. (Id. at p. 2)

B. Mr. Lieberman's Background

48. Mr. Lieberman is not qualified to offer expert testimony on internal fixation devices, fusion surgery, or biomaterials. He is a metallurgical engineer who spent thirty-four years of his career at the Boeing Company responsible for airplane design. (See Lieberman CV at Ex. E) While Mr. Lieberman seeks to offer opinions on fusion surgery, biomaterials, and internal fixation devices, he has no discernable education, training or experience in these areas. He is neither a physician nor a spine surgeon. (Lieberman Dep., p. 12 at Ex. S) He has never consulted or testified before on any implantable surgical device case. (Id. at 29) He does not have any education training or experience in the field of medical devices. (Id. at 35) He has never been employed by or consulted for a company that designs, manufactures or tests medical devices. (Id. at 35) He has never designed a medical device. (Id. at 35-36) He has never conducted a clinical trial of a medical device. (Id. at 37) He is not a member of any professional organizations

that deal with medical devices. (Id. at 36) He has never published any scientific papers with respect to medical devices. (Id. at 36) He has never studied and has no formal training in the field of biomechanics. (Id. at 8, 21) He has never studied the application of metal in an implantable surgical device. (Id. at 9) He has no formal training in orthopedics and has never observed a surgical procedure. (Id. at 20) He has never taught or given any lectures on spinal surgery, orthopedic surgery, medical devices, biomechanics or the effect of blood, body tissue and bone on implantable surgical devices. (Id. at 22-23) He has never written any peer reviewed articles on these topics. (Id. at 23) Mr. Lieberman has no expertise in testing implantable medical devices or analyzing the cause of the breakage of a surgical screw. (Id. at p. 147, 150)

49. Although Mr. Lieberman is proffered to offer quasi-medical opinion testimony concerning the process of spinal fusion and what role the ATB plays in that process, he has no training, education or experience in this area. (See Lieberman September 24, 2009 Report, p. 2 at Ex. G) His June 17, 2009 and September 24, 2009 reports are rife with errors which reveal his lack of knowledge in this area. For example, in the Opinions section of his June 2009 report, he writes that the ATB screw "was implanted in the S1 disc" and at page 2 of his September 2009 report, he writes that the ATB is placed between the two discs. (Id.) In fact, the ATB screws are implanted in the vertebrae not the discs and the

ATB is placed between the two vertebrae not between the discs. (Levine Dep., p. 17 at Ex. R; see also July 2005 Operative Report at Ex. J)

50. At deposition, Mr. Lieberman also revealed his lack of relevant knowledge of spinal fusion surgery. He testified that he needed to "look up on the internet to understand the structure of the spine, just to get a feel exactly where was this implant done. So I did a little bit of homework on that, just to basically see a sketch of the spine and how it's identified." (Lieberman Dep., p. 38 at Ex. S) He testified that he has no expertise with respect to the steps a surgeon takes to implant a spinal fusion device. (Id. at 39) He has no expertise with respect to how spinal fusion surgery is supposed to reduce a patient's pain. (Id. at 53-54)

51. Mr. Lieberman never heard of a basic tenet of fusion surgery i.e. the "race to fusion." (Lieberman Dep., p. 59-62 at Ex. S) He has never studied medical journals, orthopedic textbooks or other materials about the race to fusion. (Id. at 59-62)

52. Mr. Lieberman has never heard of the term stress shielding, a key concept in designing internal fixation devices. (Lieberman Dep., p. 64 at Ex. S) Stress shielding is a concept that in designing a medical device to aid fusion you do not want to make the device so strong that the load will be borne entirely by the device rather than the bones. (Spielman Aff., ¶ 14 at Ex. H; Zardiackas Aff. ¶ 8 at Ex. I) Bones need to be stressed by load in order to create a solid fusion.

53. Mr. Lieberman demonstrated a lack of knowledge of the purpose of the interbody device/spacer that was used by Dr. Levine and to which Dr. Levine testified and Dr. Spielman attested is the key part of achieving fusion. (Levine Dep., p. 16-20 at Ex. R; Spielman Aff., ¶ 8 at Ex. H) He mistakenly states that the ATB rather than the interbody device/spacer is the main support for the fusion process. (Lieberman Dep., p. 291, 332 at Ex. S) As testified to by Dr. Levine and attested to by Dr. Spielman, this is demonstrably false.

C. Mr. Lieberman's Methodology

54. Plaintiff's expert suggests that Synthes should have used alternative manufacturing methods, shot peening and gray anodization, which he speculates would have improved the ATB's fatigue life. However, these claims are speculative because Mr. Lieberman has not performed any testing to validate that the methods would improve fatigue life without compromising the form, fit and function of the ATB. He also suggests that Synthes should have used a dye penetrant inspection which he claims may have revealed a surface flaw in the ATB's screws if one was present. As with his other theories, Mr. Lieberman has never tested the process to assure biocompatibility and safety.

a. Shot Peening

55. Mr. Lieberman's first alternative manufacturing method is called "shot peening." According to Mr. Lieberman shot peening is a process "in which

the surface of a component is bombarded with small spherical particles of metal, glass, or ceramic. Each piece of shot striking the metal surface acts as a tiny peening hammer imparting to the surface a small indentation or dimple. To create this dimple, the surface the layer must yield in tension. Below the surface, the bulk metal in attempting to regain it original shape generates a compressive stress in the cold worked surface." (Lieberman Sept. 2009 Report at p. 3 at Ex. G)

56. In his report and at deposition, Mr. Lieberman admitted that his alternative design plan for shot peening exists solely in his mind and has not been committed to paper. He testified as follows:

Q. Have you come up with any design plan?

A. Yes.

Q. Does it exist in written form, on a piece of paper?

A. Right now, today, no.

Q. So it exists in your mind?

A. Yes.

(Lieberman Dep., p. 77-78 at Ex. S)

57. Mr. Lieberman testified that, because he has not tested shot peening on an exemplar ATB screw or any other cancellous bone screw or even held an exemplar ATB in his hand, he cannot state to what extent it would in fact have improved the fatigue life of the ATB screw as he claims. He testified as follows:

> Q. Engineering methodology would require coming up with design drawings, manufacturing of a screw based upon those drawings, and then testing to determine whether, in fact, the hoped for goal, a better screw, has been achieved or not, correct?
>
> A. Certainly.
>
> Q. That hasn't been done by you in this case?
>
> A. Of course not. (Lieberman Dep., p. 86 at Ex. S)
>
> Q. Let's talk about design modifications. You would, as part of the design modifications, use shot peening, correct?
>
> A. Right.
>
> Q. And you haven't done tests to determine whether that would improve surgical outcome, but you believe it would. Fair statement?
>
> A. What I said is that it would give a much higher probability of the screw lasting longer than it did.
>
> Q. Can you quantify how much longer?
>
> A. No, I cannot.
>
> Q. Much higher could be five percent higher, fifty percent, ninety percent. There's no way to tell until you test?
>
> A. That is true, but there would be an improvement. (Lieberman Dep., p. 124)

58. Mr. Lieberman also has not tested whether shot peening the screw, i.e. making it stronger, may negatively affect bone growth and fusion in a patient through a process known as “stress shielding”. (Lieberman Dep., p. 182-183 at Ex. S) Stress shielding, as set forth above, is a well-known concept in the field of internal fixation devices and fusion surgery. As attested to by Dr. Spielman, “a

surgeon does not want a device that will shield the graft site from loading. This is called stress shielding where the device, rather than the graft site, handles the majority of the load that a person places on his spine. It is generally accepted that stress shielding inhibits rather than aids fusion." (Spielman Aff. ¶ 14 at Ex. H) Dr. Zardiackas also attested to the concept. He stated "if the construct is too large or too strong, it may limit the load bearing of the bone, a process called stress shielding. This would impede bone healing and fusion and thus be contrary to the goal of fusion surgery." (Zardiackas Aff. ¶ 8 at Ex. I)

59. Demonstrating that Mr. Lieberman is testifying out of his area of expertise, he testified that he is not familiar with the concept of stress shielding and he does not believe there would be any negative impact on fusion if the medical device permanently takes the entire load and no load is transferred to the bones. (Lieberman Dep., p. 121, 179 at Ex. S)

60. Mr. Lieberman has also not ruled out whether a cancellous bone screw, like the screws used in the ATB, could be shot peened without damaging the specially-designed threads of the screw which are crucial for obtaining purchase within the bone. He testified as follows:

> Q. So because you've never shot peened a surgical screw of the type Synthes manufactured that's the subject in this case you can't really answer how shot peening would effect it. Fair statement?
>
> A. That's correct. (Lieberman Dep., p. 221-222 at Ex. S)

> Q. Have you, Warren Lieberman, done any testing to prove that shot peening the screws used for Mr. Jones would not change the geometrical features of the threads?
>
> A. No, I haven't.
>
> Q. Whether shot peening those screws would effect the locking mechanism for those screws, have you done any testing?
>
> A. Specifically, no. (Lieberman Dep., p. 265-266)
>
> Q. And have you done any testing or reviewed any testing which establishes that shot peening of the Synthes screws would not compromise form, fit or function?
>
> A. Have I done any testing, no. (Lieberman Dep., p. 267)

61. In fact, as attested to by Dr. Zardiackas, shot peening has a high potential to damage the threads of a cancellous bone screw, it has never been validated for such use with cancellous bone screws and he is not aware of another manufacturer which used the process for cancellous bone screws. Dr. Zardiackas states as follows:

> To my knowledge, no implant manufacturer uses shot peening for the manufacture of cancellous bone screws. Moreover, to my knowledge, the process of shot peening bone screws has not been subjected to the testing required for validation nor has it been peer reviewed for this application. The primary reason for not using shot peening for cancellous bone screws is the need to maintain the screw thread profile. The cancellous screw design used for the ATB system has a deep thread profile with very sharp edges at the crest of the thread. The deep threads are necessary to provide purchase in the cancellous bone, and the sharp edges allow the ATB screw to cut the more dense cortical bone as well as the cancellous bone. These attributes are further required since the ATB screw is a unicortical

> screw, i.e., the screw does not penetrate the far cortex of the vertebral body to prevent the possibility of screw impingement on the spinal cord. Additionally, the ATB screw has a locking thread at the head which engages the threaded holes of the ATB plate to lock the screw and prevent the screw from backing out of the plate and the bone. As a result of these requirements, damage to either of the threads would compromise the intended function of the ATB screws. Shot peening has a very high potential to damage either or both of the threads during its use. (Zardiackas Aff., p. ¶ 13 at Ex. I)

62. In lieu of testing and validation, Mr. Lieberman cites, as support for his shot peening theory, a Spring 2008 article published in a magazine called "The Shot Peener." (Ex. W) The article references a company, Medtronic, that was evaluating the use of shot peening for certain of its surgical screws, although not cancellous bone screws of the type used in the ATB.

63. The article, which was not peer-reviewed, provides insufficient support for Mr. Lieberman's opinions. First, Mr. Lieberman testified at deposition that the screws referenced in the article were made of a different material than the ATB screws. (Lieberman Dep., p. 89 at Ex. S) Second, the article states that Medtronic was still validating the process to try to meet FDA requirements. (Ex. W, p. 2) It states that the studies would first be ready in July 2008. (Ex. W, p. 2) Mr. Lieberman testified that he was not aware of a single company making spine screws who were shot peening the screws in 2005 when plaintiff's surgery took place. (Lieberman Dep., p. 217 at Ex. S)

64. Dr. Zardiackas reviewed the article on Synthes behalf. He states as follows:

> As to the article submitted by Mr. Lieberman, *Validating the Shot Peening Process*, this article was taken from a magazine not a peer reviewed scientific journal. Of greater importance, is the fact that this article only proposes that Medtronic (Sofamor Danek Group) was evaluating the possibility of using the process for spine screw applications as described in the article. Additionally the article was published in 2008, many years after the design, manufacture and implantation of the ATB screws at issue. While Mr. Lieberman suggests that Medtronic is using said new testing method, the article states that they are only performing human simulation testing to satisfy the FDA. To my knowledge, neither Medtronic nor any other implant manufacturer uses shot peening for cancellous bone screws, and I am not aware of any published peer reviewed research papers validating the process for implantable screws by Medtronic Sofamor Danek or any other implant manufacturer. (Zardiackas Aff. ¶ 14 at Ex. I)

b. Gray Anodization

65. Mr. Lieberman in his September 2009 report also opines that Synthes should have investigated the use of gray anodization. This is a process that imparts a gray color to the surface of a device, imparts increased lubricity, and increases the fatigue strength of titanium. (Zardiackas Aff. ¶17 at Ex. I)

66. As with his shot peening theory, Mr. Lieberman has done no testing to validate whether the use of gray anodization would be feasible, safe or would improve the fatigue life of cancellous bone screws of the type used in the ATB. He testified as follows:

> Q. Have you tested to determine whether gray anodization improved fatigue strength as opposed to anodization of any other color?

A. Have I tested, no.

Q. Have you reviewed any tests that demonstrate that gray anodization improves fatigue strength for screws implanted in the human spine?

A. Specifically no, the article to me summarized the data. (Lieberman Dep., p. 274 at Ex. S)

Q. Have you done any research to determine whether low friction caused by gray anodization will jeopardize a screw's holding power?

A. No. I haven't. (Lieberman Dep., p. 284)

67. As to the article referred to by Mr. Lieberman entitled *Surface Treatments of Titanium Implants*, he testified that he found it on the internet, does not know anything about the professional or academic background of its authors and does not know if the article was peer reviewed. (Lieberman Dep., p. 255-256 at Ex. S)

68. Moreover, should Synthes impart a gray color to all of its surgical screws via anodization as suggested by Mr. Lieberman, it would interfere with Synthes' ability to color code its implants and thus increase the risk of sizing errors. Further, it could negatively affect the holding power of the screws in bone because of the increased lubricity caused by anodization. Dr. Zardiackas states as follows:

> [Gray anodization], however, eliminates the ability to color code implants using anodization to reduce the possibility of sizing errors during surgery. Since the anodization process results in different

> colors to the surface based upon oxide thickness, there is no compromise related to function or biocompatibility and color coding is achieved. In the case of ATB screws, color coding to reduce the risk of sizing errors is particularly important since the screws are designed to have unicortical purchase thus eliminating impingement on the spinal cord which can result in irreversible damage and paralyzation. Moreover, using gray anodization as suggested by Mr. Lieberman, is known to increase surface lubricity which could be undesirable for a screw meant to maintain purchase and enhance the potential for bone fusion. (Zardiackas Aff. ¶ 17 at Ex. I)

c. Dye Penetrant Inspection

69. In his September 2009 report, Mr. Lieberman suggests that Synthes should have used dye penetrants as part of its inspection process to look for surface flaws in the material it uses to manufacture the screws used in the ATB. The process involves using dye penetrants to detect the presence of *surface* defects, including cracks on forged and cast medical devices which are much larger and have less tortuous surface profiles than ATB screws.

70. Mr. Lieberman cites as support for the use of dye penetrants an article he found on Wikepedia. (Lieberman Dep., p. 223 at Ex. S) According to Wikepedia's website, "it is a free encyclopedia that anyone can edit." See http://en.wikipedia.org. Clearly, this is not the type of scientific material that a reliable opinion is built upon. Mr. Lieberman testified that he is not aware that dye penetrant inspection has ever been used for surgical screws. (Lieberman Dep., p. 223) He is not aware of any company that makes screws for use in spinal fusion that performs dye penetrant inspection of the screws. (Lieberman Dep., p. 223,

229) He also testified that ultrasonic testing, which is performed by Synthes' titanium suppliers, looks at not just the surface like a dye penetrant inspection, but instead, examines the totality of the metal. (Lieberman Dep., p. 225, 277) He further testified that, since the ATB screws remain in plaintiff, he has no basis to state that a surface flaw was present.

71. Mr. Lieberman has performed no analysis as to whether it is feasible or safe to use dye penetrants on a screw meant for implantation in the human body. (Lieberman Dep., p. 238 at Ex. S) He testified that he has not done any testing to determine whether you can dye penetrant test the ATB screws and completely remove the chemical residue from the screws. (Lieberman Dep., p 268) He is also not aware of whether the solvents used in dye penetrant testing are biocompatible with humans. (Lieberman Dep., p. 271-272)

72. In fact, dye penetrant testing is not feasible or safe for surgical screws of the type used in the ATB. Dr. Zardiackas states as follows:

> Mr. Lieberman also suggests that Synthes should have used dye penetrants as part of its inspection process to look for cracks in the material it uses to manufacture the screws used in the ATB. Dye penetrants are generally used to detect the presence of surface defects, including cracks on forged and cast medical devices which are much larger and have less tortuous surface profiles. The major drawback with the use of this process is the difficulty of cleaning the surface of the device after examination. Any manufacturer of implantable medical devices must follow the principle of "Do no harm". In light of this principle, no substance which is not biocompatible or might interfere with the sterilization process can remain on the surface. The ATB screw at issue not only has threaded

> areas which must be clean and sterile but also the head and hexagonal slot for the screw driver must be clean and sterile. The presence of any dye penetrants which may be trapped especially at the line intersection between the walls and base of the hexagonal area is not acceptable and poses an unacceptable risk to the patient. To my knowledge, the use of dye penetrants for this particular application has never been tested, validated, nor peer reviewed as an acceptable technique for the inspection of cancellous bone screws.
>
> It is also important to note that the practice of the titanium suppliers, who provide titanium to Synthes, is to provide certified titanium and titanium alloy bar stock for the production of screws for implantation and to perform x-ray or ultrasonic inspection of the bar stock prior to certification and shipment to implant manufacturers including Synthes. This process essentially eliminates the possibility of defects, including cracks in the wrought bar from which the screws are machined. It is highly improbable that a crack could arise during the machining process. (Zardiackas Aff. ¶ 15-16 at Ex. I)

d. Synthes tested the ATB in accordance with government and industry standards.

73. Mr. Lieberman, in his initial report, claimed that Synthes did not adequately test the ATB to determine its fatigue life. He asserts that Synthes' testing should have accounted for all the normal variables, body weight, patient movement, variables in surgical procedure, that the ATB would encounter in a patient. (See Lieberman June 2009 report at Ex. F)

74. Synthes tested the ATB, as per industry and FDA standards, by running both a static axial test and a dynamic axial compression/tension fatigue test to 10,000,000 cycles. (See ATB test results at Ex. O: SYNTH001738 – SYNTH 1742; Deposition of Benjamin Barrall, p. 60-62 at Ex. T) Since the ATB

did not fail at 10,000,000 cycles the test is stopped and the device is not tested to breakage. Mr. Lieberman cites no support in his report for his claim that the test should have been run to breakage.

75. Moreover, at deposition, Mr. Lieberman testified that, despite the claim in his report, he was not aware of a test that could account for all the variables that a device may encounter after it is implanted in a patient. (Lieberman Dep., p. 158-159 at Ex. S) Dr. Zardiackas agrees:

> It is also not possible to determine how long a device designed for this type of application will last either as a function of time or as a number of cycles because the load for each cycle imposed on the implant by an individual cannot be determined. The reason for this dilemma is that no two patients have the same anatomy or physiology, nor do they impose the same variable load spectrum on a device which has been implanted. (Zardiackas Aff. ¶ 4 at Ex. I)

CONCLUSION

76. As set forth above and in the attached memorandum of law, summary judgment should be granted in favor of Synthes because plaintiff cannot make out a prima facie case under the NJPLA; in the alternative, an Order should be issued precluding plaintiff's expert, Warren Lieberman, from testifying in this matter, or for a *Daubert* hearing to assess the admissibility of the opinions proffered by this expert.

Dated: New York, New York
February 26, 2010

Respectfully Submitted,

By: s/ Christopher Keale

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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

----------x

ROBERT JONES and KRISTA JONES,

Plaintiffs,

-against-

SYNTHES USA SALES, LLC,
SYNTHES USA PRODUCTS, LLC,
JOHN DOES 1-5, and ABC CORP. 1-5,

Defendants.

----------x

Civil Action No.: 08 CV 2060 (JAP)

ORDER

THIS MATTER having been opened to the Court by Sedgwick, Detert, Moran & Arnold, attorneys for defendants, SYNTHES USA SALES, LLC and SYNTHES USA PRODUCTS, LLC ("Synthes") for an Order, pursuant to Rule 56 of the Federal Rules of Civil Procedure, granting summary judgment in favor of defendants dismissing plaintiff's Complaint with prejudice; or, in the alternative, an Order, pursuant to Federal Rules of Evidence Rules 702 and 703, precluding plaintiff's expert, Warren Lieberman, from testifying in this matter, or for a *Daubert* hearing to assess the admissibility of the opinions proffered by this expert; and the Court having considered Synthes' motion and all opposition papers, and for good cause shown,

IT IS on this ___ day of _____, 2010,

ORDERED, that, Synthes' motion for summary judgment is GRANTED/DENIED and all claims asserted in plaintiff's complaint are hereby DISMISSED WITH PREJUDICE;

or

ORDERED, that, Synthes' motion to preclude plaintiff's expert, Warren Lieberman, is GRANTED/DENIED and all claims asserted in plaintiff's complaint are hereby DISMISSED WITH PREJUDICE;

or

ORDERED, that, Synthes' motion for a Daubert hearing as to the admissibility of the opinions of Warren Lieberman is GRANTED/DENIED; and the parties shall contact the Court within seven (7) days of this ORDER to schedule a mutually convenient date for a Daubert hearing.

AND IT IS FURTHER ORDERED, that a copy of this order be served upon all counsel of record within seven (7) days of the date hereof.

SO ORDERED:

_____

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

----------x

ROBERT JONES and KRISTA JONES,

Plaintiffs,

-against-

SYNTHES USA SALES, LLC, SYNTHES USA PRODUCTS, LLC, JOHN DOES 1-5, and ABC CORP. 1-5,

Defendants.

----------x

Civil Action No.: 08 CV 2060 (JAP)

PROOF OF MAILING AND CERTIFICATE OF SERVICE

DOCUMENT ELECTRONICALLY FILED

I, BARRY GERSTMAN, hereby certify and affirm that a true and correct copy of the attached **NOTICE OF MOTION, AFFIRMATION IN SUPPORT AND EXHIBITS AND PROPOSED ORDER** was served via regular mail and electronically on this 26th day of February, 2010, upon the following:

White & Williams LLP
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LibertyView
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s/Barry Gerstman
BARRY L. GERSTMAN (BLG-3691)